

EFFICACY REVIEW

Product(s): **Generation Mini Blocks**

Date: February 11, 2005

EPA Reg No(s): 7173-218

DP Bar code(s): D312660

Chemical Code: Difethialone 128967

Formulation(s): Difethialone loose grain bait

Purpose for Review: The purpose for this review is to address the request to amend the product label to incorporate directions for use in sewers and burrows and to add directions necessary for wrapped bait mini blocks. The letter of request, 2 formulations for the difethialone mini blocks, and a revised label were received in my office February 2, 2005.

Good Laboratory Practices:No

Branch Chief: Meredith Laws

Team Leader: John Hebert, Product Manager 07

IRB Reviewer: Geraldine R. McCann, Biologist

BACKGROUND: The Generation Mini Block product EPA Reg No 7173-218 was registered October 24, 1995. Reviews to support the 7173-218 product were done by B. Jacobs on the following dates taken from the jacket: October 24, 1995, September 20, 1996, September 20, 2001, and December 31, 2001. The letter addressing the latest testing (MRID 454620101 and 45462002) dated October 23, 2001, discusses the need to verify the baits used for this test and describe the process by which the rats and mice were fed amounts of bait not consistent with package sizes. The 100% repack of this product is the Generation Wrapped Mini Block (EPA Reg No 7173-235). The studies quoted to support this product and 7173-218 were the weathered bait studies: MRID 45462001 and 45462002 dated July 26, 2001.

Response to Response from Letter dated 12 August 2004:

The latest label approved for the product claimed as “nearly identical” (7173-236 Difethialone Mini Blocks) was approved on December 16, 2004; however, this aforementioned label does not mention burrows or sewers.

The MRIDs 45462001 and 45462002 previously submitted to support the “weathered” bait on rats and mice, respectfully, were reviewed by B. Jacobs on

September 20, 2001. In the review for the rats (45462001), it is noted that B. Jacobs states:

“Bait was offered to the test-group rats in quantities of “50 g/cup 1 cup/cage”. As the blocks of 7173-218 are supposed to be 20 g each, LiphaTech must explain how they arrived at “50 g/cup”. Altering the shape of the blocks or crumbling them would mean that the test material was not the product being offered for sale as 7173-218. (The product’s label does not direct cutting, breaking, or crumbling of the bait blocks, leaving the obvious inference that they are to be applied as they come.) As protocol 1.213 prohibits removal of mold from weathered baits, any doctoring of baits to reach a target initial weight could further compromise the test.”

In his conclusion(s) for the product 7173-235 (Generation Wrapped Mini Block - 100% repack of 7173-218 Generation Mini Block), B. Jacobs states: “The 15-day Norway Rat wrapper penetration efficacy report (MRID 455491-02 is acceptable for the purpose of indicating that rats will chew through a bait block’s wrapper and feed to their demise. The results of the study apply only to the specific wrapper that was used in the study.”

In the review for the mice (45462002), it is noted that B. Jacobs states:

“Bait was offered to the test-group mice in quantities of “25 g/cup 4 cups/cage”. As the blocks of 7173-218 are supposed to be 20 g each, LiphaTech must explain how they arrived at “25 g/cup”. Altering the shape of the blocks or crumbling them would mean that the test material was not the product being offered for sale. (Even for house mice, the label does not direct cutting, breaking, or crumbling of the bait blocks, clearly implying that they are to be applied as they come.) As protocol 1.214 prohibits removal of mold from weathered baits, any doctoring of baits to reach a target initial weight could further compromise the test.”

In his conclusion(s) for the product 7173-235 (Generation Wrapped Mini Block - 100% repack of 7173-218 Generation Mini Block), B. Jacobs states: “The 15-day house mouse wrapper penetration efficacy report (MRID 455491-01 is acceptable for the purpose of indicating that rats will chew through a bait block’s wrapper and feed to their demise. The results of the study apply only to the specific wrapper that was used in the study.”

**EFFICACY
COMMENTS**

1. The Batch/Lot Number formulations (00301 and 12301) dated January 3, 2001, and May 2, 2001, respectively, submitted in support of 7173-218 are acceptable.

EFFICACY

2. The description of the Difethialone Mini Block application during

COMMENTS
(Cont.)

the testing period for the studies (MRID 45462001 and 45462002 as described by J. Hanson dated August 27, 2004, is a deviation from the guidelines (1.213 for rats and 1.214 for mice, respectfully). The handling and administration of the test substance was described as follows:

“To obtain 50 grams, two whole blocks plus a portion of another block were needed. Portions were obtained by splitting a block by cutting it with a knife through the center hole. Each day the unconsumed portion was collected from within and underneath the cages. The unconsumed portion was weighed and either thrown away or replenished with additional new blocks (or pieces of new blocks) to achieve 50 grams. Large chunks of test substance were generally retained, while crumbled or fouled spillage was disposed of. At no point was mold ever scraped off the blocks or intentionally disturbed.”

B. Jacobs states in his September 20, 2001 review for these products that: “Altering the shape of the blocks or crumbling them would mean that the test material was not the product being offered for sale as 7173-218.”

The tests representing MRIDs 45462001 and 45462002 for rats and mice, respectfully, are accepted because the Lot/Batch number of the bait is acceptable and in his review, B. Jacobs states: “...the composite acceptance figure exceeded the criterion of 25% for tests with weathered bait.”

3. All of the tests involving the bait for the EPA Reg. No 7173-218 (Generation Mini Blocks) with and without a wrapper (MRIDs 45549101 and 45549102, and 45462001 and 45462002, respectfully), are considered acceptable.

Conclusion(s): The submission to support the claims for use in sewers and burrows is acceptable providing the same wrapper is being used on the “individually wrapped” Mini Blocks as was accepted to register “Generation Wrapped Mini Blocks”, EPA Reg No 7173-235. .